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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/480,389	01/11/2000	Bruce M. Boman	CATX-N	4258

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/480,389	BOMAN, BRUCE M.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *81-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *81-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/2005 has been entered.

1. The amendment filed 10/26/2005 is acknowledged. Claims 24-28, 32-35, 37-44, 55-57 and 59-72 were canceled without prejudice. Claims 81-103 were added.

Claims 81-103 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The rejection of claims 24-28, 32-35, 37-44, 55-57 and 59-72 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the cancellation of the claims.

4. The rejection of claims 24-28, 32-35, 43, 44, 55-57, and 61 under 35 U.S.C. 103(a) as being unpatentable over Pece (Pece, N. et al. J. Clin. Invest. 100(10): 2568-2579, 1997, November; cited in IDS) in view of Nozawa (U.S. Patent 5,328,826; issued July 12, 1994; filed March 23, 1992) is withdrawn in view of the cancellation of the claims.

New Grounds of Rejection:

5. Claims 81-103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 81 is indefinite because of the use of the term "wild-type". The scope of the claim is not clear because this term appears to be used interchangeably in the specification with "full-length". However, in the art, "wild-type" protein usually refers to a protein having a specific sequence. In the this case, do the claims read on methods where polymorphisms are distinguished?

6. Claims 81-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bodily fluids that contain cells, does not reasonably provide enablement for bodily fluids that do not contain cells (e.g. serum). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation

necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The claims are drawn to methods comprising preparing a lysate of normal cells, preparing a protein extract from the lysate of normal cells and then immunologically quantitating the levels of two or more wild-type subject proteins. The specification and claim 87 specifies that various bodily fluids may be the biological sample containing the normal cells. One of the named bodily fluids is serum, which is not a bodily fluid that contains cells. Serum is the fluid that remains after the blood cells are clotted from a sample of blood or plasma. Therefore, it does not appear that the claimed methods are enabled by the specification for the practice of the claimed inventions to the extent the claimed inventions read on the use of serum as a source of the normal cells.

7. Claims 81-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for screening for hereditary colorectal cancer comprising immunologically quantitating the levels of tow or more subject proteins, where the subject proteins are selected from the group consisting of MLH1, MSH2, MSH6, PMS1 and APC, does not reasonably provide enablement for where the subject proteins include PMS2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The specification teaches that the claimed methods are based on the theory of gene dosage effects on protein levels. Therefore, if an individual has a mutation in one of the subject genes and the protein level of that subject gene is detected and compared to the protein level of a second subject gene that the ratio of the first subject gene to the second subject gene will be 50% of the ratio if the sample were taken from an individual without a mutation. The assumption underlying this method of using one subject gene as a control for another is that only rarely would an individual have a mutation in more than one subject gene. However, this does not appear to be the case for PMS2. Gill teaches that selective loss of PMS2 expression is a rare phenotype (occurring in only 4.3% of MSI-H tumors), and that PMS2 loss of expression is consistently seen whenever MLH1 expression is lost (see Gill, S. et al., Clin. Cancer Res. 11(18):6466-6471, 2005; see page 6468-6469, bridging paragraph). In view of the fact that the specification does not contain data for the measurement of PMS2 ratios with respect to any the subject genes included in claimed methods, it does not appear that the claimed methods are useful if one of the subject genes is PMS2. Therefore, with respect to methods using PMS2 as one of the subject genes, the specification does not appear to enable the claimed methods.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Tuesdays, Wednesdays and Fridays, 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
January 22, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER